Purpose of Report

The enactment of Senate Enrolled Act 450 (SEA 450) by the 2007 General Assembly places a moratorium on new opioid treatment programs in Indiana through December 31, 2008. In addition to other matters, SEA 450 requires the Indiana Family and Social Services Administration (FSSA) Division of Mental Health and Addiction (DMHA) to: (1) compare other state regulations of methadone clinics with Indiana regulations; (2) address concerns that have been raised concerning Indiana's regulation of methadone clinics; and (3) prepare a report to be submitted to the Health Finance Commission and the General Assembly, before July 1, 2007.

Indiana Regulation of Opioid Treatment Programs

The Indiana Family Social Services Administration (FSSA) Division of Mental Health and Addiction (DMHA) is responsible for certifying addiction treatment service providers under Indiana Code IC 12-23-1-6 and Indiana Administrative Code 440 IAC 4.4. In 1992, the Indiana General Assembly enacted IC 12-23-13-2, which provides: Prescribing, dispensing, or administering controlled substances for treatment of drug abuse. DMHA Certification and Licensure section enforces the certification requirements in conjunction with approved accrediting bodies: the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Commission on Accreditation of Rehabilitation Facilities (CARF), and the Council on Accreditation (COA), which are also approved by the federal government as accrediting bodies, as required by Code of Federal Regulations, 42 CFR Part 8.[1] The federal regulations in 42 CFR Part 8 are the responsibility of the U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), Division of Pharmacologic Therapies (DPT). DMHA serves as the federally required State Authority (SA),[2] also referred to as State Methadone Authority (SMA). This two-level regulation by federal (SAMHSA) and state (DMHA) agencies is mandated through 42 CFR Part 8, the federal regulations for Certification of Opioid Treatment Programs (OTP). The term OTP has replaced “methadone clinics” since these programs may use alternative medications.

In **Indiana**, all opioid treatment programs (OTPs) are required to: (1) meet federal regulations 42 CFR Part 8; (2) receive State Authority (SA) approval; (3) obtain certification under 440 IAC 4.4; (4) apply for and receive accreditation from a SAMHSA and DMHA approved accrediting body; (5) obtain a Controlled Substances Registration to administer the controlled substances methadone and buprenorphine from the U.S. Department of Justice Drug Enforcement Administration (DEA) under 21 CFR Parts 1301 et seq., and; (6) obtain a Controlled Substances Registration Certificate from the Indiana Professional Licensing Agency Board of Pharmacy with approval of the

[1] *Federal Register*, January 17, 2001
[2] *Code of Federal Regulations*, 42 CFR Part 8.11(c)(1)

Controlled Substances Advisory Committee (CSAC). [3] These approvals, accreditation, registration and certification processes must be renewed regularly. Currently, Indiana OTPs are also regulated by DMHA under Indiana Code IC 12-23-18 Methadone Diversion Control and Oversight Program.[4]

Approximately 70% of the 45 states (including Puerto Rico and the District of Columbia) which allow establishment of OTPs have rules that are more stringent than the federal regulations.[5] Among the states which have more stringent regulations are the four states contiguous to Indiana (Illinois, Kentucky, Michigan and Ohio).

Prevalence of Opiate Addiction and Effectiveness of Opioid Treatment

In 2004, an estimated .1% (166,000) of the US population age 12 and older used heroin, and 2% (4.4 million) used pain relievers, including other opiates, for non-medical reasons[6]. The prevalence of addiction to opiates obtained both medically and illicitly has been raised as a concern by the public and health care practitioners.[7] Opioid addiction treatment utilizing an opiate agonist medication has been identified as "the most effective treatment for opioid dependence, serving more than 200,000 patients in the United States".[8] In 2006, similar surveys estimated that there were approximately 1,093 OTPs serving 250,000 people.

Indiana's experience with opioid addiction treatment dates back to the 1970s, and outcomes measurement began formally in 1998. Over the seven year period from 1998 to 2005, OTPs experienced a growth of 167%, serving 3,704 persons in 1998 to 9,882 persons in 2005. In 2005, the most recent year for which data are currently available, Indiana's twelve operating OTPs reported the following positive outcomes of treatment:[9]

- 87.6% of patients reduced[10] use of prescription opiates;
- 88.4% of patients reduced illegal use of non-prescription opiates;
- 82.2% reduced illegal use of non-opiate drugs;
- 83.4% reduced criminal behavior;
- 85.5% reduced risky behaviors related to spread of infectious disease;
- 82.5% reduced alcohol abuse;

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[3] IC 35-48-3 and 856 IAC 2-3

[4] IC 12-23-18-1 to establish and administer a methadone diversion control and oversight program

[5] Conversation with CSAT DPT's Nick Reuter on May 14, 2007

[6] 2004 National Survey on Alcohol and Drug Use (NSDUH), Substance Abuse and Mental Health Services Administration (SAMHSA)

[7] 2005 National Survey on Drug Use and Health (NSDUH) estimated that 379,000 Americans aged 12 and older used the illicit drug heroin in 2005, and the federal Drug Abuse Warning Network (DAWN), 2005, estimates that emergency room visits related to the non-medical use of either prescription or over-the-counter drugs increased from 475,732 to 598,542 between 2004 and 2005, nearly a 26% increase.

[8] 2003 U.S. Department of Health & Human Services, SAMHSA, "Opioid Agonist Therapy with Methadone or LAAM,", http://dpt.samhsa.gov/00110250-tx.htm

[9] 2005 Indiana Opioid Addiction Treatment Program Report, 2005, http://www.in.gov/fssa/mental

[10] from Indiana annual OTP Survey where "reduced" includes eliminated

- 36.9% improved educational/training status;
- 65% improved employment situation; and
- 83% improved family relationships.

Concerns about Indiana Regulation of OTPs

Despite the positive treatment outcomes identified, concerns are still voiced over Indiana's OTPs. These concerns have come from a wide range of individuals and groups, including Indiana State legislators, OTP patients and their families, proposed communities for new OTP facilities, media reports, and the Indiana Professional Licensing Agency's Controlled Substances Advisory Committee. Concerns are grouped into two categories: (A) Number of Out-of-State Patients Treated in Indiana, and (B) Approval Process and Administrative Requirements for Opioid Treatment Programs, and are summarized below.

A. Number of Non-Resident Indiana Patients

Data from 2005 showed that Indiana's 12 opioid treatment programs (OTPs) treated 9,882 patients.[11] Of those, 4,738 patients (47%) listed another state of residency; the majority coming from surrounding states. **Kentucky** represented 2,706 (27.38%) of patients treated while **Ohio** had 1,907 (19.3%). **Michigan** and **Illinois** supplied 50 (.51%) and 67 (.68%) patients, respectively. The out-of-state residency population in Indiana clinics has increased in numbers served, as well as, percentage of total patients. From 1998 to 2005, Kentucky residents at the Indiana OTPs increased from 774 to 2,706 (21% to 27%), while Ohio residents increased from 549 to 1,904 (15% to 19%).

1. Distribution of Non-Resident Patients across Indiana

There are no residency restrictions on patients served by Indiana's twelve opioid addiction treatment programs (OTPs). As previously mentioned, the total number of out-of-state patients served was 4,738 in 2005. All but two of Indiana's OTPs served out-of-state patients[12]. The majority of out-of-state patients (85%) were served by two OTPs.
The East Indiana Treatment Center (EITC) in Lawrenceburg accounted for 57.6% while Southern Indiana Treatment Center (SITC) in Jeffersonville served 21% of this total population. At each clinic, the percentage of out-of-state resident population varies. The EITC had 55.4% of their patients from Ohio and 37.7% from Kentucky. SITC had 66.1% of their patients from out-of-state. The remaining clinics had the following percentages of out-of-sate patients in 2005: Evansville Treatment Center (ETC) in Evansville, 51.5%; Richmond Treatment Center (RTC) in Richmond, 33%; Victory Clinical Services II in South Bend, 33%; and The Center for Behavioral Health in Fort Wayne, 13.5%. Please see table below.

[11] 2005 Indiana Opioid Addiction Treatment Program Report, 2005, http://www.in.gov/fssa/mental
[12] Midtown Narcotic Treatment Program, Indianapolis, and Holliday Health Care, Gary

2005 OTP Patients by Center and State of Residence

							Number		Total
Treatment Center Name							of Patients		# of
	IL	IN	KY	MI	OH	Other	Out of State	IN	Patients
Center for Behavioral Health Indiana, Inc.	0	437	0	1	67	0	68	437	505
Fort Wayne									
Discovery House, Inc.	7	254	0	0	0	1	8	254	262
Gary									
East Indiana Treatment Center, Inc.	0	211	1097	0	1630	3	2730	211	2941
Lawrenceburg									
Edgewater Systems for Balanced Living, Inc.	2	349	0	0	0	0	2	349	351
Gary									
Evansville Treatment Center, Inc.	47	350	326	0	0	1	374	350	724
Evansville									
Health & Hosp. Corp. of Marion County	0	359	0	0	0	0	0	359	359
Indianapolis									
Holliday Health Care, PC	0	2	0	0	0	0	0	2	2
Gary									
Indianapolis Treatment Center, Inc.	6	1399	3	1	3	3	16	1399	1415
Indianapolis									
Metro Treatment of Gary, LP	5	469	0	1	0	0	6	469	475
Gary									
Richmond Treatment Center, Inc.	0	557	0	0	205	0	205	557	762
Richmond									
Southern Indiana Treatment Center, Inc.	0	658	1280	0	2	3	1285	658	1943
Jeffersonville									
Victory Clinical Services II, LLC	0	96	0	47	0	0	47	96	143
South Bend									
Totals	67	5141	2706	50	1907	11	4741	5141	9882
Percentage of Total Patients	0.68%	52.02%	27.38%	0.51%	19%	0.11%	47.98%		100.00%
Percentage of Out of State Patients	1.41%	N/A	57.08%	1.05%	40.22%	0.23%	100.00%		

2. Factors Influencing Non-Resident Indiana Patients

Availability of OTPs in Region

Indiana has greater availability of opioid addiction treatment through OTPs than Kentucky and Ohio, but less than other contiguous states proportionate to the general population.

State	Centers	Population[13]	Ratio of Centers to Population	Patients Treated[14]
Illinois	54	12,653,544	1:234,325	11,564
Indiana	13	6,195,643	1:476,587	9,882
Kentucky	8	4,117,827	1:514,728	1,935
Michigan	36	10,079,985	1:280,000	7,100
Ohio	11	11,435,798	1:1,039,618	3,062

OTP Locations

Another factor influencing patients to come to Indiana for treatment is the location of the OTPs. Patients' right to treatment is a strong value of SAMHSA, the federal agency which has regulatory authority over OTPs including elimination of state lines as a barrier to treatment. Out-of-state residents living near the Indiana border are often closer to an Indiana OTP than one in their home state. For example, Cincinnati and Northern Kentucky has a population exceeding two million people[15] but only one small public OTP in Cincinnati. Other than Lawrenceburg, that area's closest Kentucky OTP is 74 miles away in Lexington. Another example is Niles, Michigan. The closest OTP for Michigan patients is just ten miles away in South Bend, Indiana. The closest OTP in Michigan is 22 miles away in Benton Harbor. The same proximity is true for other areas of Kentucky, Illinois and Ohio. The proximity is compounded by the fact that patients often work in cities near the borders.

Cost of Treatment, Insurance Coverage and Indigent Care

The cost of treatment may also be factor in an out of state patients' decisions to come to Indiana for their opioid addiction treatment. Indiana and its four contiguous states provide some financial assistance in the form of indigent care and sliding fee scales utilizing federal Substance Abuse Prevention and Treatment (SAPT) block grant funds. Indiana Medicaid may provide limited coverage for OTP services. Kentucky Medicaid does not

[13] 2003 U.S. Bureau of Census estimates
[14] 2005 U.S. Department of Health & Human Services, SAMHSA, Treatment Episode Data Set (TEDS)
[15] 2003 U.S. Bureau of Census estimates

pay for OTP treatment. Medicaid programs in Illinois, Michigan and Ohio offer varying coverage to individuals for treatment. Very few patients receive insurance coverage for services, which adds to the burden of cost.

Michigan provides public funds for its for-profit and not-for-profit OTPs.[16] The state utilizes managed care entities as gatekeepers for entry into all OTPs. The OTPs are eligible to access Medicaid and federal SAPT block grant funds. These clinics can also receive payment from private insurance.

Indiana, Illinois, Kentucky and Ohio provide public funds only to not-for-profit OTPs. **Indiana** directly funds two not-for-profit OTPs from SAPT block grant funds to subsidize certain patients, based upon income limitations and reduces out-of-pocket costs to these patients through a sliding scale. **Ohio**'s not-for profit OTPs accept Medicaid and offer a sliding fee scale. Ohio Medicaid covers opioid addiction treatment, both medication administration at $16.38 per dose, and counseling. The average cost per patient to Medicaid is $1,600. **Kentucky'**s not-for-profit OTPs subsidize the treatment cost through federal block grant funds. The Kentucky Medicaid program does not cover opioid addiction treatment. **Illinois**' not-for-profit OTPs manage "slots" funded by the federal SAPT block grant and charge additional client fees on a sliding scale. These programs are encouraged to move clients to non-funded slots as they become employed.

As of July 1, 2007, Indiana has eleven for-profit and two not-for-profit OTPs in operation. In 2005, Indiana's not-for-profits enrolled 710 patients (7.2%) and ten for-profits enrolled 9,712 patients (92.8%). CRC Health, Inc. operates five Indiana OTPs, served 7,213 patients (84.3%). One new OTP opened in March 2007 in Marion, Indiana. The table below outlines the OTPs currently in operation.

State	Not-for-Profit OTPs	For-Profit OTPs	Total OTPs
Illinois	32	22	54
Indiana	2	11	13
Kentucky	2	6	8
Michigan	8	28	36
Ohio	11	0	11

Waiting Lists in Other States

Indiana's OTPs allow admissions on a demand basis. Some neighboring states have limited patient "slots" which may result in patients needing treatment traveling to an out-of-state OTP that will accept them immediately. Waiting lists are understood to occur in Kentucky, Michigan, and Ohio. In 2006, Kentucky's nine OTPs served just fewer than 2,000 patients and Ohio's eleven OTPs served just over 3,000. In Kentucky and recently in Michigan, staff-to-patient ratios have also been a factor in curtailing admissions.

[16] Spring, 2007, estimate is that 6,000 of Michigan's 7,500 annual patients treated receive care at least partially subsidized through public funds

B. Administrative Requirements

The federal CSAT DPT regulations[17] set baseline requirements for opioid treatment programs. There are variations in each state's approval process and administrative/operational requirements as outlined below. Indiana has not yet promulgated opioid addiction treatment program rules, but a few of these issues have been addressed in State law.

1. Approval Process

Indiana's process for approving opioid addiction treatment programs has been addressed in Indiana State law. Some states have placed their approval processes in state rules.

Restrictions on Type of Entity Qualified to Apply to Establish an OTP

Federal regulations require that in addition to State approval, all OTPs must be approved by SAMHSA CSAT and the Drug Enforcement Administration. The state variations are outlined below.

Indiana's approval process initially begins with program certification as an Addiction Service Provider.[18] Additional requirements for approval were placed in statute in 2006.[19] The statute allows entities to apply to establish an OTP in counties with a population of 40,000 or more, where no OTP exist. Prospective applicants must submit a needs assessment demonstrating that a "heroin or other opiate problem" exists to the extent that there is a need for treatment. There is a statutory moratorium on acceptance of applications through the end of 2008.

Ohio requires that entities applying or maintaining a license to operate an OTP be owned and operated by an alcohol and drug treatment program that has been certified by Ohio for a minimum of two years. In **Kentucky,** applicants must be licensed as a substance abuse treatment program. There are no restrictions for **Illinois** or **Michigan** applicants.

Process for Establishing Need for OTPs

Indiana has no formal determination of need process for OTP treatment capacity. During the 2006 application review process utilized by DMHA, the needs assessment had to demonstrate that a minimum of 75 county residents needed an OTP. **Kentucky** requires applicants to document the need for an OTP. Currently, **Illinois** and **Ohio** have no determination of need process. **Illinois** is exploring this option in case more than one applicant requests to establish a program in the same locale. **Michigan** requires opioid addiction treatment service to be available through its 16 regional managed care entities.

[17] 42 CFR Part 8
[18] 440 IAC4.4
[19] P. L. 28-2004 Section 191

Demonstration of Community Support for Establishing an OTP

Indiana requires applications for a new OTP to include community endorsements from high-ranking locally elected public officials or appointed law enforcement from the county where the OTP would be established. Recently, two approved OTPs received strong endorsement from local officials. In Indiana, local zoning officials become involved with applicants where the location is contested. **Illinois** requires applicants to demonstrate that the community, including local government officials and community organizations, are aware of the application and are at least neutral, if not approving. **Kentucky** requires demonstration of community support through letters of support from relevant area agencies, and the public has the right to request a public hearing to discuss the program's interest in establishing an OTP in the community. **Ohio** does not have any requirements. **Michigan** relies on local zoning boards to approve establishment of OTPs, which provides a vehicle for local communities to raise concerns during the zoning approval process.

2. Operational Requirements

The federal regulations require OTPs to have an organizational structure and facility adequate to ensure quality patient care and to meet the requirements of all pertinent federal, State and local laws and regulations. OTPs are required to formally designate a program sponsor and medical director. The sponsor agrees on behalf of the OTP, to adhere to all requirements set forth in the federal regulations. The medical director assumes the responsibility for administering all medical services performed by the OTP as well as assuring the OTP is in compliance with all applicable federal, state and local laws and regulations.

Indiana OTPs are currently abiding by the federal regulations on the issues outlined. These are issues which may be considered in Indiana oversight rules for opioid addiction treatment programs required by IC 12-23-18-1. The significant operational differences between Indiana and contiguous states follow:

Program Staffing Requirements

Indiana follows the federal regulations which defer to accreditation standards on this matter and do not currently specify staff-to-patient ratios. **Kentucky** and **Michigan** have established staff-to-patient ratios for certain staff positions. This is a program cost and patient access issue which impacts treatment availability and can result in waiting lists. **Kentucky** requires OTPs to employ counseling staff at a staff-to-patient ratio of 1:40. Physician-to-patient ratio must be 1:300. **Michigan** has a physician hour-to-patient ratio of 1:30; a nurse-to-patient ratio of 1:150; a counselor-to-patient ratio of 1:40; and a physicians' assistant-to-patient ratio of 1:100. **Illinois** and **Ohio** do not have required staff-to-patient ratios for OTPs.

Staff Qualifications

Indiana follows the federal regulations which defer to accreditation standards on this matter which require that staff have sufficient education, training and experience or any combination thereof to enable them to perform designated functions. Physicians, nurses and other licensed professional care providers, including counselors, must comply with the credentialing requirements of their respective professions, although Indiana does not have state license or certification of addiction counselors.

States contiguous to Indiana have all established **program counselors** staff qualifications requirements that are more stringent than the federal requirements. **Illinois** requires its counselors to be certified by the Illinois Counseling Board after two years of employment. Counselors working toward certification must have their work counter-signed by a certified counselor. **Kentucky** requires counselors to have a bachelors' degree in related human services as well as obtained, or actively engaged in the process of obtaining, an alcohol and other drug (AOD) counselor certification from the Kentucky Board of AOD Counselors. **Ohio** counselors must be licensed by the state as an AOD counselor. **Michigan** counselors must pass a state test on fundamentals of substance abuse counseling as well as any local county requirements.

Indiana and all four contiguous states rely on state licensing and certification requirements for Physicians and Nurses. **Kentucky** requires medical directors to either be board-eligible psychiatrists with three years' experience in the practice of addiction medicine or to be certified by the American Society of Addiction Medicine (ASAM). **Indiana**, **Illinois**, **Michigan,** and **Ohio** place no further demands on medical directors beyond the federal regulations.

Hours of Operation

Indiana follows the federal regulations on take home medication distribution which require an OTP to be open a minimum of six days per week with Sunday the usual day closed. They also allow for closure on the eight major holidays. The federal regulations do not include hours of operation restrictions. Only **Kentucky** requires OTPs remain open seven days a week, and none of the other states contiguous to Indiana specifies the hours of operation.

Admitting Privileges to Hospitals

Indiana follows the federal regulations and accreditation standards which require that collaborative agreements exist between OTPs and providers of ancillary services. This assures that patients have access to services identified as important to their success in treatment and recovery. None of the four states contiguous to Indiana requires that physicians have admitting privileges to local hospitals. They do have collaborative agreements between local service providers and OTPs to assure patient access to emergency medical care.

Regulatory Fees

There are no federal regulations regarding fees. The federal government does not charge fees for OTP certification. However, all approved accrediting organizations (JCAHO, CARF and COA) charge fees for the accreditation requirement set forth by federal regulations. **Indiana** does not charge fees for certification of AOD programs. However, beginning in 2003, Indiana law[20] requires OTPs to pay a $20 annual fee for each out-of-state patient into the Methadone Diversion Control and Oversight (MDCO) Program fund, administered by DMHA. **Michigan** charges no fees for establishment of OTPs. Oversight is funded through federal Substance Abuse Prevention and Treatment (SAPT) block grant and other public funds. **Illinois** charges a license fee of $200 for three years, which goes to the state general fund. Program oversight funds come from the federal SAPT block grant and certain state allocations. **Kentucky** charges an annual licensing fee of $75, which goes to the Office of Inspector General. This Office enforces Kentucky's methadone rules. Kentucky's State Methadone Authority oversight functions are paid out of state appropriations or federal SAPT block grant funds. **Ohio** does not charge establishment fees. Since all Ohio OTP's are not-for-profit, administrative oversight expenses are paid by federal SAPT block grant funds.

Central Patient Registry

Federal regulations require that OTPs document a "good faith effort" to review whether a patient is simultaneously enrolled in more than one OTP. **Indiana** reviews the OTPs for this requirement during annual site visits. Indiana is establishing an electronic central opioid addiction treatment program registry. This will allow OTPs to immediately validate an incoming patient's status at any other Indiana OTP and prevent enrollment in more than one Indiana program at a time. Indiana is working on a mechanism for other states to access the system once it is operational in the fall of 2007. **Illinois** and **Kentucky** have central electronic patient registries, with Kentucky's new system created by the University of Kentucky Center for Drug and Alcohol Research. Once Indiana's electronic system is operational discussion may begin to allow access to each other state's central registry. **Ohio** and **Michigan** do not operate a central opioid addiction treatment patient registry.

3. Program Flexibility

Federal Regulations set forth OTP baseline program standards. It is very specific in many areas, including, but not limited to, admission criteria, medication administration and dispensing protocols, frequency of patient drug testing, referrals for ancillary services, and granting of take-home medication privileges. The federal regulations also establish pregnant women as a priority population for services and require OTPs to provide specialized services for pregnant women (i.e. prenatal care). There are two areas that are not addressed precisely in the regulations, but only through accreditation

[20]IC 12-23-18-3.

standards: frequency and amount of counseling provided patients, and the tapering off, replacing or discontinuing of the opiate agonist medication.

Patient Counseling Requirements

Indiana follows the federal regulations which defer to accreditation standards on requirements for substance abuse counseling provided by program counselors as clinically necessary. Counseling must be provided on preventing exposure to and transmission of HIV disease and OTPs must provide, either directly or by referral, adequate and accessible community resources, vocational rehabilitation, education and employment services for patients who request or need these services. Lastly, the patient's treatment plan must include the frequency with which these services will be provided, and the plan must be updated to include the patient's needs in all the areas.

Some states have placed more stringent requirements on OTPs than the federal regulations regarding patient counseling. **Kentucky** utilizes a five-phase system, each lasting a minimum of 90 days. Entry and Phase I: patients must be seen individually weekly; Phases II and III: patients must be seen individually monthly; and Phase IV: individual sessions are based on clinical judgment. It is important to note that Phase IV begins when the patient has completed two years in treatment and all other phase requirements have been met. **Ohio** patients are required to attend counseling sessions as long as they are receiving methadone as a medication. **Michigan**'s OTPs are overseen by three state agencies, each with separate requirements, and patients are required to be seen based on individual need as specified in their treatment plan. **Illinois** places no further demands on methadone programs regarding counseling of patients.

Take-Home Medication

Indiana follows the federal regulations which establish clear directions on take-home medication privileges. Each program's medical director grants these privileges based on the eight-point criteria. The criteria include: 1) absence of recent abuse of drugs/alcohol; 2) regularity of clinic attendance; 3) absence of serious behavioral problems at the clinic; 4) absence of known recent criminal activity; 5) stability of the patient's home environment and social relationships; 6) length of time in treatment; 7) assurance that take-home medication can be safely stored in the patient's home; and 8) whether the rehabilitative benefit of decreasing clinic visits outweighs the potential risks of medication diversion.

Patients can begin with no more than a single take-home dose per week during the first ninety days of treatment working up to a month's supply after two continuous years of treatment. It also requires that patients are visiting the clinic at specified intervals. This assures continued positive response to treatment, plan modifications and provides opportunities for supportive counseling. Drug testing is required, including testing for the presence of methadone, to prevent diversion. The federal regulations do allow for exceptions to the take-home schedule, based on the medical director's assurance that the

patient is meeting the eight-point criteria and only with approval by SAMHSA and the State Authority.

All four states contiguous to Indiana have placed restrictions beyond those in the federal regulations on program allowance of take-home medication doses. **Illinois'** rules are the least restrictive, but do require that the State Methadone Authority approve qualified patients for monthly take-home privileges (receipt of 30 doses at a time). **Ohio** follows the federal regulations until the patient has been in treatment for at least one year, but does not allow more than a two-week take-home supply for patients after a year in treatment. In addition to the eight-point federal take-home criteria, Ohio considers regularity of clinic attendance at counseling sessions and employment status when reviewing a patient's qualification for take-home medication privileges. **Kentucky** has established a five-phase system, as previously mentioned. Each phase lasts a minimum of 90 days and requires urine drug screening throughout. Phase I: patients report to the clinic six days a week; Phase II: five days a week; Phase III: three days a week and receive no more than three dosages; Phase IV: patients report to the clinic two days a week and still receive no more than three take-home doses. If at any time the patient's urine drug screen indicates drug use, the patient is moved back at least one phase for not less than 30 days. Take-home privileges are also automatically restricted if the urine drug test finds the absence of methadone or if the patient commits another program infraction. **Michigan** patients can begin take-home privileges after 90 days of successful treatment six days a week. Patients are allowed to reduce onsite dosing to three per week and can receive no more than two take-home dosages. After two years, patients may be allowed to reduce onsite dosing to two times per week and can receive no more than three take-home dosages. After three years, patients may qualify for up to six take-home dosages, providing they come to the clinic at least once a week. Michigan allows exceptions to these requirements under exceptional circumstances requested by the physician.

Discontinue or "Taper-Off" Treatment

Federal regulations do not require patients to be "tapered off" of opiate agonist medication (methadone/buprenorphine), and state that the clinically appropriate dose is administered to the patients and they are periodically assessed to determine appropriateness of treatment continuation. There are three prevailing addiction treatment options for heroin and other opiate-dependent patients; opioid detoxification, opioid agonist maintenance, and opioid antagonist maintenance. Opioid detoxification, or tapering, minimizes withdrawal symptoms to prevent illicit use. Opioid agonist maintenance prevents withdrawal, reduces cravings, eliminates or reduces illicit opiate use, and prevents or reduces euphoria from illicit opiates though a receptor blocking effect. Opioid antagonist maintenance produces an abrupt withdrawal, accompanied by medically supervised sedation at times, then prevents or reduces euphoria from illicit opiates though a receptor blocking effect. The only available opioid antagonist agent is Naltrexone. The use of Naltrexone has been relatively unsuccessful when compared with opioid agonist therapy.

The federal regulations use the term "maintenance treatment" or “detoxification treatment” when describing patient admission criteria. Patient qualification for detoxification admission must be determined by the program physician. The federal regulations allow maintenance opioid addiction treatment for patients that have at least one year of documented opiate addiction. Long term opiate use has been documented to alter brain chemistry.

Neither **Indiana** nor any of the four contiguous states require that OTPs discontinue or “taper-off” opioid addiction treatment to their patients. **Kentucky** requires the medical director to review and justify continued treatment for patients who have been in treatment for 24 months. Kentucky also has a policy defining a patient's right to taper or discontinue treatment, but the policy does not require patients to taper-off medication. **Michigan** provides financial subsidies to patients for two years, after which time they are expected to be employed and pay for treatment, or tapered off. **Illinois** and **Ohio** have no additional regulations.

Analysis

As noted in this report, the policies regarding the operation and procedure for planning, development, implementing, and regulating programs for the treatment of opioid dependency varies from federal and between Indiana and contiguous states. These differences may contribute to the issues experienced in communities where OTPs are located and to border communities where neighboring states have large underserved populations. This report should prompt Indiana policy makers to provide direction for a comprehensive policy in the delivery of opioid treatment programs that best serves the citizens of Indiana and addresses how non residents may be served.

Information included in the report was collected by staff at the Division of Mental Health and Addiction.